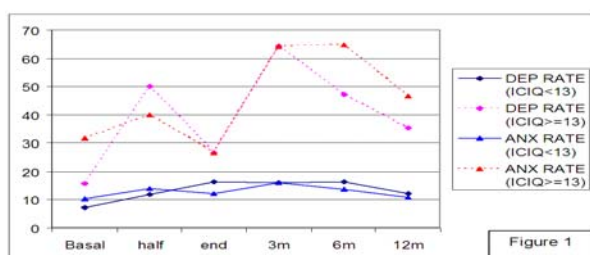


between ANX \geq 8/DEP \geq 8 rates during/after RT vs BSL. The impact of ICIQ/IPSS scores, as well as that of BSL ANX/DEP, on the risk of ANX \geq 8/DEP \geq 8 at 6-12 months was tested in a logistic regression model.

Results: The rates of ANX \geq 8 did not differ from BSL at any time, though an increase was found at 3-6 months (6 months vs BSL: 23.3% vs 14.8%, $p=0.12$). On the contrary, DEP \geq 8 was significantly higher during and after RT (6 months vs BSL: 22.2% vs 8.8%, $p=0.02$; difference at 12 months not statistically significant). No impact on ANX \geq 8/DEP \geq 8 of RT intent, fractionation, AAD or RT technique emerged at any time.

ANX \geq 8 at 6-12 months was predicted by 2-variable models including BSL ANX and ICIQ scores at corresponding times or, alternatively, at RT end, with high discriminative power (AUC ranging between 0.86 and 0.90). The same variables also predicted DEP \geq 8 at 6 months (AUC=0.88). A further analysis showed that the changes in ANX \geq 8/DEP \geq 8 over time are highly modulated by ICIQ score (Figure1).



Conclusions: Incontinence, during and after PoP WPRT, and baseline ANX/DEP are major factors in increasing the risk of clinically significant anxiety/depression. End RT ICIQ score is a good predictor of increased risk of ANX/DEP at 6-12 months.

Debate: Should participation to databases be made mandatory

SP-0322

For the motion

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Clinical decision is a complex moment and, as stated by Sir W.Osler, 'Medicine is a science of uncertainty and an art of probability'.

Medical doctors foster their 'internal databases of knowledge' by daily clinical practice, but time-by-time their performances question their capacity to storage and to communicate data, as well as to act efficiently.

The rapid learning technology is nowadays supporting the transfer of this process to 'external databases of knowledge', with the aim to have less individual variability in the understanding of the knowledge and more reliability in the prediction of the outcomes.

By rapid-learning technology data routinely generated through patient care and clinical research feed into an ever-growing databank or set of coordinated databases. The health care system "learns" by routinely and iteratively collecting data in a planned and strategic manner, generating evidence through retrospective analysis of existing data as well as data from prospective studies and generating new hypotheses for investigation.

Even if many issues in term of data definition, accuracy and interoperability are still to be solved this approach is not mandatory: it is unavoidable!

SP-0323

Against the motion (for randomised trials)

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SP-0324

For the motion rebuttal

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SP-0325

Participation to databases should not be made mandatory

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Big multi-institutional medical databases will be technically feasible in near future. The validity of such databases critically depends on uniform coding and comprehensive registration of all clinical relevant information including toxicity and long term follow up. Provided all technical problems and data protection issues could be solved, the question arises what kind of conclusion could be drawn from these databases for clinical oncology. Databases will give in realistic overview how cancer patients are treated in specific situations including the presumably high variability of the applied treatments. Clinical outcome data including toxicity and survival would give an impression, what can be achieved with currently available treatments. The widespread use of these databases will likely result in some potentially unbeneficial changes in clinical practice and a number of risks, if statistical analysis is preformed and causal interpretations is pursued. The universal availability of clinical outcomes in a big database will led to smaller variations of actually applied treatments, since presumably favorable treatments would be identified in these databases, and physician would prefer to prescribe, what most other physician prescribe in the same situation. These presumably favorable treatments were likely influenced by a number of biases resulting from preconceptions of the oncological community. Innovative treatments initiated by single investigators or institutes that don't follow the preconceptions of the majority of the oncological community maybe hampered, if mainstream treatments derived from big databases are easily accessible for home physicians and patients. The risk that knowledge from big databases in absence of evidence from randomized trials results in self-fulfilling prophecies is high. One important risk of misinterpretation results from the fact that clinical databases do typically not allow to perform an intent to treat analysis. Since complete documentation of all potentially criteria involved in treatment decisions cannot be comprehensively documented in a clinical database, the risk of misinterpretation is high. Propensity scores have been proposes to correct for these biases, but are unable to correct for unknown relationships. Whenever causal interpretations are derived from big clinical databases, one needs to be aware that interpretation requires a high degree of caution. Results from clinical big databases should be regarded as hypothesis generating and cannot at all be considered as substitute for randomized clinical trials. Forcing physicians, who have no intrinsic motivation, to